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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,878	10/31/2003	Takashi Komai	2003-1593A	9005

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SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER

BLAND, LAYLA D

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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11/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/697,878

Applicant(s)

KOMAI ET AL..

Examiner

Layla Bland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is a response to applicant's amendment submitted August 6, 2007, wherein claim 8 is cancelled, claims 1, 4, 7, and 9 are amended, and new claim 13 is added. In the response to restriction requirement dated November 6, 2006, applicant elected Group I, drawn to an anti-coagulant comprising a polysaccharide. New claim 13 is drawn to a method of treatment and thus is withdrawn from consideration. Claims 1-7 and 9-13 are pending in this application. Claims 11-13 are withdrawn from consideration as being drawn to non-elected inventions. Claims 1-7, 9, and 10 are examined on the merits herein.

In view of the cancellation of claim 8, all rejections made with respect to that claim in the previous office action are withdrawn.

In view of Applicant's amendment submitted August 6, 2007, the rejection of claim 9 under 35 USC 112, first paragraph, is withdrawn.

In view of Applicant's amendment submitted August 6, 2007, the objection to claim 9 as being in improper multiple dependent form is withdrawn.

The following rejections of record are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyamoto et al. (International Journal of Biological Macromolecules, 2001; cited in IDS).

Miyamoto et al. disclose the preparation of GS from gellan wherein the hydroxyl groups are sulfated (page 382, 1st col., 2.2). The reference does not indicate that the degree of sulfation is between 8-80% however the results are shown where the degree of sulfation is up to 40%, particularly 16%, 25%, and 35% (page 383, Fig.3 and page 384, Table I). It is inherent property of a gellan polysaccharide to undergo sulfation up to 100% in a sulfation reaction through its available hydroxyl groups. Furthermore, it is well known in the art that the constituent sugars of gellan are glucose, glucuronic acid and rhamnose in the molar ratio of 2:1:1. Miyamoto et al. also disclose the Formula (I) of claim 2 (page 383, Fig.2).

Claims 1-4 are product-by process claims. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964,

966 (Fed. Cir. 1985) (citations omitted). The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113. Therefore, Miyamoto et al's GS is encompassed by the applicants' claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamoto et al. (International Journal of Biological Macromolecules, 2001; cited in IDS).

Miyamoto et al. teach the preparation of GS from gellan wherein the hydroxyl groups are sulfated (page 382, 1st col., 2.2). Miyamoto et al teach that GS can be used as a biomedical selective artificial ligand for use in removing a complex of extra domain A containing fibronectin (FN) from plasma in rheumatoid arthritis patients because the high selectivity of GS property for EDA(+)FN as an artificial ligand probably depends on the saccharide conformation, sulfuric groups density and position of gellan that closely relates with the sulfuric and carboxyl groups (page 384, last para.). The reference does not indicate that the degree of sulfation is between 8-80% however the results are

shown where the degree of sulfation is up to 40%, particularly 16%, 25%, and 35% (page 383, Fig.3 and page 384, Table I). It is inherent property of a gellan polysaccharide to undergo sulfation up to 100% in a sulfation reaction through its available hydroxyl groups. Furthermore, it is well known in the art that the constituent sugars of gellan are glucose, glucuronic acid and rhamnose in the molar ratio of 2:1:1. Miyamoto et al. also disclose the Formula (I) of claim 2 (page 383, Fig.2). With regard to the very broad ranges of mean molecular weight of the sulfated polysaccharide between 1 to 1000 or 1 to 30 KDa of claims 5 and 6, Miyamoto et al's GS discloses the average unit number (n) of gellan between 50-100 (page 383, Fig.2), which would very likely correspond to molecular weights which fall within the claimed ranges, and it would be within the scope of the artisan in this art to optimize them through routine experimentation in the absence of unexpected results with a particular combination. Miyamoto et al. also discloses the solubility of GS in buffer medium in the study of their affinity constant (page 382, 2nd col.), it would be within the scope of the artisan in this art to optimize the GS preparation in a buffer suitable for intravenous administration, intestinal administration or oral administration through routine experimentation. It is noted that GS is structurally close to an anti-thrombus agent heparin because in both of these polysaccharide the hydroxyl groups are partially sulfated therefore GS can also be used as an anti-thrombus agent due to inherent properties of the sulfated polysaccharide.

Claims 5-7, 9, and 10 are product-by process claims. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability

is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113. Therefore, Miyamoto et al's GS renders obvious applicants' claimed invention.

Response to Arguments

Applicant's arguments filed August 6, 2007 have been fully considered but they are not persuasive.

Applicant argues that Miyamoto et al. do not disclose or suggest that the raw material polysaccharide is hydrolyzed before sulfation. Applicant argues that this pretreatment of the polysaccharide results in lowering the molecular weight of the polysaccharide.

As set forth above, “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different

process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Indeed, Miyamoto et al. do not disclose the use of hydrolyzed polysaccharide. However, the claimed product is still anticipated by, or rendered obvious by, Miyamoto et al. The instant specification states that hydrolysis can be used to produce a product of “low molecular weight.” “Low molecular weight” is a relative term. Miyamoto et al. teach a product of 50 unit numbers, which is “low” compared to a product having more than 50 unit numbers, and which corresponds to a molecular weight which very likely falls within, or is very near to, the molecular weight ranges recited in claims 5 and 6. Thus, it is seen that the claimed product is the same as, or obvious from the product taught by Miyamoto et al.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Layla Bland
Patent Examiner
Art Unit 1623
November 19, 2007

Shaojia Anna Jiang

Supervisory Patent Examiner
Art Unit 1623
November 19, 2007